

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

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CONTROLLING DRUG DELIVERY APPARATUS**
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ATTENTION: Board of Patent Appeals and Interferences

APPEAL BRIEF (37 C.F.R. § 41.37)

Appellants hereby submit this Appeal Brief appealing the rejection of claims 1, 3, 7, 8, 12, 13, 16-21, 39-41, 44, and 51-63 of the present application, the Notice of Appeal for which was filed on June 17, 2010.

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I. REAL PARTY IN INTEREST (37 C.F.R. § 41.37(c)(1)(i))

The real party in interest in this appeal is PROFILE RESPIRATORY SYSTEMS LIMITED, which is the assignee of record for this application via assignments recorded on April 26, 2001 at reel/frame 011749/0099, August 7, 2001 at reel/frame 012053/0305, and October 15, 2004 at reel/frame 015962/0454.

II. RELATED APPEALS AND INTERFERENCES (37 C.F.R. § 41.37(c)(1)(ii))

There are no other related appeals, interferences, or judicial proceedings known to Appellants, Appellants' legal representatives, or Assignee which may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS (37 C.F.R. § 41.37(c)(1)(iii))

A. Status of All Claims in the Application

1. Claims pending: 1, 3, 7, 8, 12, 13, 16-21, 39-41, 44, and 51-63.
2. Claims rejected: 1, 3, 7, 8, 12, 13, 16-21, 39-41, 44, and 51-63.
3. Claims allowed: none.
4. Claims canceled: 2, 4-6, 9-11, 14, 15, 22-38, 42, 43, and 45-50.
5. Claims withdrawn from consideration (e.g., by election/restriction) but not canceled: none.
6. Claims objected to: none.

B. Claims on Appeal

Appellants appeal the rejection of pending claims 1, 3, 7, 8, 12, 13, 16-21, 39-41, 44, and 51-63.

IV. STATUS OF AMENDMENTS (37 C.F.R. § 41.37(c)(1)(iv))

Appellants have not filed an After-Final Amendment.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER (37 C.F.R. § 41.37(c)(1)(v))

Appellants provide the following concise, non-limiting explanation of example subject matter of appealed independent claims 1, 13, 19-21, 39, and 40 with parenthetical citations to the original application:

1. A drug package comprising:

at least one container {ref. 8; p. 8, line 1; FIGS. 1, 4} containing a drug for delivery to a patient in a drug delivery device {refs. 10, 50; p. 7, lines 1-3; p. 15, line 9; FIGS. 1, 5}; and

an electronic data carrier {refs. 5, 53; p. 7, line 5; p. 15, line 12; FIGS. 1, 5} removable from the at least one container, the carrier including a memory {p. 7, line 13} holding drug treatment information for use by the drug delivery device, the electronic data carrier further includes a radio frequency device {p. 7, lines 13-26} for transmitting the drug treatment information to the drug delivery device.

13. A drug delivery device comprising:

a delivery portion {refs. 10, 50; p. 7, lines 1-3; p. 15, line 9; FIGS. 1, 5} for delivering a drug to a patient;

an electronic input {ref. 4; p. 7, line 4; FIG. 1} arranged remotely from the delivery portion and configured to receive treatment information from a removable electronic data carrier {refs. 5, 53; p. 7, line 5; p. 15, line 12; FIGS. 1, 5} wherein the input is a radio frequency receiver configured to receive the treatment information from the electronic data carrier over a radio frequency signal; and

a delivery controller configured to control the amount of the drug delivered to the patient based on the received treatment information {p. 8, line 28, to p. 11, line 32}.

19. An assembly comprising:

a drug delivery device {refs. 10, 50; p. 7, lines 1-3; p. 15, line 9; FIGS. 1, 5};

an electronic data carrier {refs. 5, 53; p. 7, line 5; p. 15, line 12; FIGS. 1, 5} for use with the drug delivery device and removable from the drug delivery device, the electronic data carrier comprising:

a memory {p. 7, line 13} located within the electronic data carrier, the memory holding drug-specific treatment information concerning the use of the drug delivery device in delivering a specified drug, and

an output {p. 7, lines 13-26} configured to transmit the drug-specific treatment information via a radio frequency signal from the memory to the drug delivery device.

20. A drug delivery system comprising:

a drug delivery device {refs. 10, 50; p. 7, lines 1-3; p. 15, line 9; FIGS. 1, 5} for delivering a drug, the drug delivery device having a medication chamber {ref. 8; p. 8, line 1; FIGS. 1, 4} for receiving a drug for delivery and an electronic input {ref. 4; p. 7, line 4; FIG. 1} for receiving treatment information relating to the drug; and

an electronic data carrier {refs. 5, 53; p. 7, line 5; p. 15, line 12; FIGS. 1, 5} removable from the drug delivery device including a memory {p. 7, line 13} for storing the drug treatment information for use by the drug delivery device, the carrier also includes an output {p. 7, lines 13-26} for transmitting the treatment information to the electronic input,

wherein the input is a radio frequency input which is configured to receive the treatment information from the electronic data carrier over a radio frequency signal {p. 7, lines 13-23}, whereby the drug delivery device is configured to deliver the drug in conformity with the treatment information {p. 8, line 28, to p. 11, line 32}.

21. A method of operating a drug delivery device comprising:

supplying a plurality of containers {p. 9, lines 31-33}, each container of the plurality of containers containing a drug for use with the drug delivery device;

supplying an electronic data carrier {refs. 5, 53; p. 7, line 5; p. 15, line 12; FIGS. 1, 5} removable from the plurality of containers, the electronic data carrier includes treatment information {p. 10, line 30, to p. 11, line 5};

transmitting the treatment information from the electronic data carrier to the drug delivery device {p. 7, lines 13-23};

placing an amount of the drug from a container of the plurality of containers in the drug delivery device {p. 8, lines 5-7}; and

delivering the drug in accordance with the treatment information from the data carrier {p. 8, line 28, to p. 11, line 32}.

39. A drug package comprising:

a plurality of drug containers {p. 9, lines 31-33}, each container containing a drug for delivery to a patient in a drug delivery device; and

an electronic data carrier {refs. 5, 53; p. 7, line 5; p. 15, line 12; FIGS. 1, 5} separate from the drug containers, the carrier including drug treatment information for use by the drug delivery device wherein the data carrier is a radio frequency device and wherein the data carrier is arranged to be powered inductively from a radio frequency signal transmitted from or associated with the drug delivery device {p. 7, lines 13-23}.

40. A drug package comprising:

a plurality of drug containers {p. 9, lines 31-33}, each container containing a drug for delivery to a patient in a drug delivery device; and

an electronic data carrier {refs. 5, 53; p. 7, line 5; p. 15, line 12; FIGS. 1, 5} separate from the drug containers, the carrier including drug treatment information for use by the drug delivery device wherein the data carrier is a radio frequency device, wherein the data carrier is arranged to be powered inductively from a radio frequency signal transmitted from or associated with the drug delivery device, and wherein the data carrier is arranged to generate the radio-frequency signal bearing the treatment information.

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL (37 C.F.R. § 41.37(c)(1)(vi))

Appellants appeal each of the following rejections:

- A. the rejection of claims 1, 3, 4, 7, 8, 12, 19-21, 54, 57-60, 62, and 63 under 35 U.S.C. § 102(b) as anticipated by Gordon (U.S. Patent No. 4,617,557);
- B. the rejection of claims 39-41, 44, 48, and 61 under 35 U.S.C. § 103(a) as obvious over Gordon in view of Chartrand (U.S. Patent No. 5,562,550); and
- C. the rejection of claims 1, 13, 16-19, And 51-56 under 35 U.S.C. § 103(a) as obvious over Anderson (U.S. Patent No. 5,237,987) in view of Gordon.

VII. ARGUMENT (37 C.F.R. § 41.37(c)(1)(vii))

A. The Rejection Of Claims 1, 3, 4, 7, 8, 12, 19-21, 54, 57-60, 62, And 63 Under 35 U.S.C. § 102(b) As Anticipated By Gordon

Claims 1, 3, 4, 7, 8, 12, 19-21, 54, 57-59, 60, 62, and 62 were rejected under 35 U.S.C. § 102(b) as anticipated by Gordon (U.S. Patent No. 4,617,557). Appellants traverse this rejection for the following reasons.

1. Independent Claim 1

Appellants traverse this rejection of claim 1 for several reasons.

First, claim 1 recites, among other things, “a drug for delivery to a patient in a drug delivery device.” In contrast, Gordon discloses only “tablets” or “capsules” capable of being dispensed via a “blister packages” and then ingested by a patient. *See* Gordon, col. 1, line 47. Patients take such “tablets” and “capsules” by hand, rather than by “delivery to a patient in a drug delivery device,” as recited in claim 1. Thus, Gordon’s tablets/capsules are not “for delivery to a patient in a drug delivery device,” as recited in claim 1.

The Office Action responds by asserting that Gordon satisfies this functional recitation because “it is well known in the art that capsules can carry powders and that powders can be inhaled.” 4/2/10 Office Action, p. 2, ¶ 2. Appellants traverse this assertion for several reasons.

The Office Action’s assertion that Gordon’s capsules “carry powders” is essentially an assertion that the capsules inherently contain powder, particularly because Gordon never discloses that the capsules do contain powder that can be inhaled, much less inhaled via delivery by a drug delivery device. “A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim.” *Metabolite Laboratories, Inc. v. Laboratory Corporation of America Holdings*, 370 F.3d 1354, 1367, 71 U.S.P.Q. 2d (BNA) 1081, 1090 (Fed. Cir. 2004) (quoting *EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350, 60 U.S.P.Q. 2d (BNA) 1423, 1429 (Fed. Cir. 2001) (citation omitted)). According to the MPEP:

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

MPEP 2112(IV) (quotations/citations omitted; underlining in original). In contrast, the capsules in Gordon do not “necessarily” contain powder, as would be required to sustain the Office Action’s implicit inherency assertion. Indeed, the Office Action acknowledges as much by merely asserting that Gordon’s capsules “can carry powders,” rather than that Gordon’s capsules necessarily do carry powder. 4/2/10 Office Action, p. 2, ¶ 2 (underlining added). The Office Action has therefore failed to demonstrate the inherency required to assert that Gordon discloses an inhalable powder in the capsule. As a result, Gordon fails to disclose a drug capable of “delivery to a patient in a drug delivery device,” as recited in claim 1.

Regardless of whether inhalable powder is inherently in Gordon’s capsules, the Office Action’s anticipation rejection relies on a proposed modification to Gordon by removing the powder from the capsule so as to make it capable of “delivery to a patient in a drug delivery device,” as recited in claim 1. This recognition that a modification would have to be made to Gordon’s disclosed capsule in order to satisfy the recitations of claim 1 proves that the anticipation rejection is improper.

Moreover, the proposed modification could not form the basis of a proper obviousness rejection because it would not have been obvious to so modify Gordon’s capsules so as to make them capable of “delivery to a patient in a drug delivery device,” as recited in claim 1. The drug in Gordon’s “tablets” or “capsules” is inherently designed to be ingested whole. It would not have been obvious to have deviated from the intended delivery method, as proposed by the Office Action.

Further still, it would not have been obvious to adapt Gordon’s device to a “drug for delivery to a patient in a drug delivery device,” because Gordon is entirely focused on blister packages containing tablets/capsules for ingestion. *See* Gordon, col. 2, lines 10-25 (“The present invention discloses a method and apparatus ... particularly suitable for use with individual dosage packaging, such as blister packs.”).

Second, claim 1 recites, among other things, that “the electronic data carrier further includes a radio frequency device.” The Office Action alleges that Gordon discloses an electronic “data carrier [64]” and a “radio frequency device 70.” 4/2/10 Office action, pp. 5-6.

However, the alleged radio frequency device 70 is not part of the alleged electronic data carrier 64, as required to satisfy claim 1. To the contrary, the radio frequency device 70 is entirely separate from the alleged electronic data carrier 64.

Third, claim 1 recites, among other things, that “a radio frequency device [of the electronic data carrier] for transmitting the drug treatment information to the drug delivery device.” Gordon fails to disclose the transmission of drug treatment information from the asserted electronic data carrier (i.e., housing 64) to the asserted drug delivery device (i.e., the blister package) via the alleged radio frequency device 70, because Gordon teaches only the one-way communication from the radio frequency device 70 on the blister package (see Gordon, FIG. 6) to the asserted electronic data carrier 64 (see Gordon, FIG. 5). Thus, Gordon’s alleged radio frequency device 70 is incapable of “transmitting the drug treatment information” from the recited electronic data carrier (of which the recited radio frequency device is a part), as recited in claim 1.

For at least these reasons, Appellants respectfully request the reversal of this anticipation rejection of claim 1, as well as its dependent claims, which are patentable at least because they depend from a patentable independent claim.

2. Dependent Claim 57

Claim 57 recites, among other things, that “all of the drug in the first container is commonly stored in a single compartment of the first container; and the drug treatment information comprises information indicating that some, but not all, of the drug in the first container should be delivered by the drug delivery device.” In contrast, Gordon discloses that a unit dose of a drug (e.g., “capsules” or “tablets”) is stored in each single compartment (e.g., one of the compartments of Gordon’s “blister package”). Gordon, col. 1, line 47. Because Gordon focuses on such unit dose capsules/tablets, Gordon does not disclose or otherwise render obvious that “the drug treatment information comprises information indicating that some, but not all, of the drug in the first container should be delivered by the drug delivery device,” as recited in claim 57.

The Office Action responds that “the at least one container can be read as the blister pack, the first container can be considered one capsule, and the blister pack can be considered a single compartment. All the capsules are contained within the single compartment.” 4/2/10 Office Action, ¶ 18. Appellants respectfully traverse this assertion because it ignores the

additional recitation in claim 57 that “the drug treatment information comprises information indicating that some, but not all, of the drug in the first container should be delivered by the drug delivery device.” The Office Action fails to allege that Gordon discloses such a combination of recitations. Indeed, Gordon does not disclose “drug treatment information compris[ing] information indicating that some, but not all, of the drug in” Gordon’s single capsule (i.e., the alleged first container) “should be delivered by the drug delivery device.” Rather, because Gordon only tracks the use of entire capsules, and because capsules are designed to be taken whole, Gordon fails to disclose a combination including, among other things, that “all of the drug in the first container is commonly stored in a single compartment of the first container; and the drug treatment information comprises information indicating that some, but not all, of the drug in the first container should be delivered by the drug delivery device,” as recited in claim 57.

Moreover, to the extent that the Office Action ambiguously asserts that the numerous tablet/capsule compartments of Gordon’s blister package somehow comprise a “single compartment,” Appellants traverse such an assertion. The numerous discrete compartments of Gordon’s multi-compartment blister pack cannot reasonably be interpreted to be “a single compartment.” Indeed, such an interpretation is entirely inconsistent with Gordon, which focuses on keeping separate track of the presence or absence of a tablet/capsule in each individual compartment of the multi-compartment blister package, which Gordon explicitly refers to as “various dosage compartments.” Gordon, col. 4, lines 50-51; *see also id.* at FIG. 1.

Appellants note that the Office Action simultaneously asserts that Gordon’s blister package comprises “a plurality of containers.” 4/2/10 Office Action, p. 5, ¶ 17. The blister package cannot simultaneously be “a single compartment” and “a plurality of containers.”

Appellants therefore respectfully request the reversal of this anticipation rejection of claim 57 for these additional reasons.

3. Dependent Claim 12

Dependent claim 12 recites, among other things, that “the electronic data carrier further comprises a radio frequency receiver configured to receive nebulizer treatment information from the nebulizer; and the memory is configured to store the nebulizer treatment information received from the nebulizer.” Because Gordon is directed solely to manually swallowed tablets/capsules, rather than drugs delivered via a nebulizer, Gordon does not disclose or

otherwise render obvious such a combination of recitations. Appellants therefore respectfully request the reversal of this anticipation rejection of claim 12 for this additional reason.

4. Independent Claim 19

Appellants traverse this rejection of claim 19 for several reasons.

First, claim 19 recites, among other things, “a drug delivery device.” The Office Action asserts that Gordon’s blister package of tablets or capsules is a “drug delivery device.” 4/2/10 Office Action, p. 3, ¶ 7. Appellants respectfully traverse the Office Action’s assertion. A blister package is not a “drug delivery device” because it is not used to actually *deliver* the drug to the patient. The present application discloses a variety of non-limiting, exemplary “drug delivery device[s].” *See, e.g.*, the present application, p. 1, line 6, to p. 2, line 54. In view of the present application, those of ordinary skill in the art would not have considered a blister package to be a “drug delivery device.” Appellants submit that the Office Action’s interpretation is unreasonably broad in view of the specification. *See In re Suitco Surface, Inc.*, Reexamination no. 90/007,015, Appeal No. 2009-1418 (Fed. Cir. 2010) (“Although the PTO emphasizes that it was required to give all ‘claims their broadest reasonable construction[,]’ ... this court has instructed that any such construction be ‘consistent with the specification, ... and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.’”) (underlining added).

Second, claim 19 recites, among other things, “an output configured to transmit the drug-specific treatment information via a radio frequency signal from the memory to the drug delivery device.” To the extent that Gordon’s blister package comprises a “drug delivery device” (Appellants dispute this as explained above), Gordon fails to disclose, suggest, or otherwise render obvious “an output configured to transmit the drug-specific treatment information via a radio frequency signal from the memory to the drug delivery device,” as recited in claim 19. Instead, Gordon discloses only communication in the opposite direction. Specifically, Gordon teaches only the one-way communication from the blister package (see Gordon, FIG. 6) to the asserted electronic data carrier (i.e., housing 64) (see Gordon, FIG. 5). Thus, Gordon fails to disclose a combination including, among other recitations, “an output for transmitting the treatment information via a radio frequency signal from the memory [of the data carrier] to the drug delivery device.”

For at least these reasons, Appellants respectfully request the reversal of this anticipation rejection of claim 19.

5. Dependent Claim 59

Claim 59 recites, among other things, that “the drug delivery device comprises a nebulizer.” Gordon’s blister package of tablets/capsules is not a “nebulizer.” Although claim 59 is rejected as anticipated by Gordon, the Office Action fails to even allege that Gordon discloses the recited “nebulizer.”

At most, the Office Action ambiguously asserts that the “nebulizer” recitation does not limit the method claim 59 because the nebulizer does not “affect the method in a manipulative sense.” *See* 4/2/10 Office Action, p. 5, ¶ 19. Appellants respectfully traverse this assertion. Claim 59, in combination with its base independent claim 21, recites “placing an amount of the drug... in the [nebulizer]” and “delivering the drug” via the “nebulizer.” Placing a drug into a nebulizer and delivering the drug via a nebulizer is a quite different method than by ingestion of a tablet/capsule, as disclosed in Gordon. The recited use of a “nebulizer” cannot, therefore, be ignored in this method claim, and distinguishes claim 59 from Gordon.

Appellants therefore respectfully request the reversal of this rejection of claim 59 for this additional reason.

6. Dependent Claim 60

Claim 60 recites, among other things, that “the radio frequency device comprises a radio frequency transmitter configured to transmit the drug treatment information; and the drug delivery device comprises a radio frequency receiver configured to receive the drug treatment information transmitted by the radio frequency transmitter.” The Office Action asserts that Gordon discloses “a radio frequency transmitter (70) and a radio frequency receiver (74).” 4/2/10 Office Action, p. 5, ¶ 17. However, as explained above, Gordon’s transmitter (70) is part of the alleged drug delivery device (blister package), rather than the electronic data carrier, as recited by the combination of claims 19 and 60. Similarly, Gordon’s alleged radio frequency receiver 74 is part of the alleged data carrier 64, not part of the alleged drug delivery device, as recited in claim 60. *See* Gordon, col. 6, lines 59-66. Appellants therefore respectfully request the reversal of this rejection of claim 60 for this additional reason.

7. Dependent Claim 54

Claim 54 recites, among other things, that “the drug delivery device comprises an electronic input configured to receive the treatment information from the output via the radio frequency signal.” As explained above, the alleged input/receiver in Gordon, i.e., antenna 74, is not part of the alleged drug delivery device (i.e., blister package). Rather, the alleged drug delivery device includes only a transmitter 70, rather than an “electronic input configured to receive the treatment information from the output via the radio frequency signal,” as recited in claim 54. Appellants therefore respectfully request the reversal of this rejection of claim 54 for this additional reason.

8. Independent Claim 20

Appellants traverse this rejection of claim 20 for several reasons.

First, claim 20 recites, among other things, “a drug delivery device.” As explained above with respect to claim 19, Gordon does not disclose or otherwise render obvious a “drug delivery device.”

Second, claim 20 recites, among other things, that the drug delivery device has a “radio frequency input which is configured to receive the treatment information from the electronic data carrier over a radio frequency signal, whereby the drug delivery device is configured to deliver the drug in conformity with the treatment information.” As explained above, Gordon’s alleged drug delivery device (i.e., the blister package) includes no such electronic input. While Gordon’s electronic data carrier may include an electronic input, such an input is part of the electronic data carrier, which is “removable from the drug delivery device,” and is therefore not part of the recited “drug delivery device.”

For at least these reasons, Appellants respectfully request the reversal of this anticipation rejection of claim 20.

9. Independent Claim 21

Appellants respectfully traverse this rejection as applied to claim 21 for several reasons.

First, claim 21 recites, among other things, a “drug delivery device.” As explained above with respect to claim 19, Gordon’s blister packages are not a drug delivery device.

Second, claim 21 recites, among other things, “transmitting the treatment information from the electronic data carrier to the drug delivery device.” To the extent that Gordon’s blister

package is a drug delivery device (Appellants dispute this), Gordon fails to disclose the transmission of drug treatment information from the asserted electronic data carrier (i.e., housing 64) to the asserted drug delivery device (i.e., the blister package). Rather, as explained above, Gordon only teaches communication in the opposite direction, i.e., from the blister package (see Gordon, FIG. 6) to the asserted electronic data carrier (i.e., housing 64) (see Gordon, FIG. 5). Thus, Gordon fails to disclose a combination including, among other recitations, “transmitting the treatment information from the electronic data carrier to the drug delivery device,” as recited in claim 21.

For at least these reasons, Appellants respectfully request the reversal of this anticipation rejection of claim 21.

B. The Rejection Of Claims 39-41, 44, 48, And 61 Under 35 U.S.C. § 103(a) As Obvious Over Gordon In View Of Chartrand

Claims 39-41, 44, 48, and 61 were rejected under 35 U.S.C. § 103(a) as obvious over Gordon in view of Chartrand (U.S. Patent No. 5,562,550). Appellants traverse this rejection for the following reasons.

1. Independent Claim 39

Appellants traverse this rejection of claim 39 for several reasons.

First, claim 39 recites, among other things, that “a drug for delivery to a patient in a drug delivery device.” As explained above with respect to claim 1, Gordon does not disclose a “drug for delivery to a patient in a drug delivery device,” as recited in claim 39. Chartrand does not cure this deficiency.

Second, claim 39 recites, among other things, that “the data carrier is arranged to be powered inductively from a radio frequency signal transmitted from or associated with the drug delivery device.” The Office Action concedes that “Gordon fails to teach wherein the data carrier is arranged to be powered inductively from a radio frequency signal,” but asserts that it would be obvious to convert Gordon’s direct battery power to such an inductively powered system in view of Chartrand because battery and inductive power “are [obvious] expedients of each other.” 4/2/10 Office Action, p. 7, ¶¶ 21-22. Appellants traverse such an assertion. Gordon powers its electronic data carrier 64 via a direct wired battery 20 within the carrier. In contrast, Chartrand uses more complicated inductive power so as to avoid having a battery in a credit-card sized electronic card 16. Chartrand, col. 6, lines 58-60. Chartrand relies on power

from a large, powered base unit with a magnetic field generating antenna 18. Chartrand, col. 7, lines 4-15. Because Chartrand's reasons for using inductive power are not present in Gordon, and because the proposed modification would significantly complicate Gordon and make Gordon less reliable, without any countervailing benefit, the proposed modification would not have been obvious.

Specifically, the Office Action essentially proposes moving Gordon's battery 20 from the electronic data carrier 64 to the attached blister package (the alleged drug delivery device) and then transmitting the battery's power back to the electronic data carrier 64 via inductive power. However, there was no obvious reason to transfer the battery from the electronic data carrier 64 to the blister package and then transmit power back to the electronic data carrier via inductive powering. Indeed, because the electronic data carrier 64 is designed to be remote from the blister package, such a modification would defeat the purpose of the providing such remote operation because inductive powering would require the electronic data carrier and blister package to be very close to each other in order for Chartrand's magnetic flux to be sufficiently strong to power the electronic data carrier 64. *See* Chartrand, col. 7, lines 6-13. Thus, Gordon teaches away from such a modification because it would defeat Gordon's goal of enabling the electronic data carrier 64 to be remote from the blister package. MPEP 2143.01(V) ("If proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."); MPEP 2145(X)(D)(2) ("It is improper to combine references where the references teach away from their combination.") (citation omitted); MPEP 2143.01(VI) ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.").

For at least these reasons, Appellants respectfully request the reversal of this obviousness rejection of claim 39, as well as its dependent claims, which are patentable at least because they depend from a patentable independent claim.

2. Dependent Claim 61

Claim 61 recites, among other things, that "the radio frequency device comprises a radio frequency transmitter configured to transmit the drug treatment information to the drug delivery device." In contrast, as explained above, Gordon's alleged data carrier includes no radio frequency transmitter. Chartrand does not cure this deficiency, as it is merely relied upon by the

office action for inductive power. Appellants therefore request the reversal of this rejection of claim 61 for this additional reason.

3. Independent Claim 40

Appellants traverse this rejection of claim 40 for several reasons.

First, claim 40 recites, among other things, that “a drug for delivery to a patient in a drug delivery device.” As explained above with respect to claim 1, Gordon does not disclose a “drug for delivery to a patient in a drug delivery device,” as recited in claim 40. Chartrand does not cure this deficiency.

Second, claim 40 recites, among other things, that “the data carrier is arranged to be powered inductively from a radio frequency signal transmitted from or associated with the drug delivery device.” As explained above with respect to claim 39, it would not have been obvious to modify Gordon in view of Chartrand so as to satisfy this combination of recitations.

Third, claim 40 recites, among other things, that “the data carrier is arranged to generate the radio-frequency signal bearing the treatment information.” The Office Action does not even assert that the proposed combination of Gordon and Chartrand would result in such a combination of recitations. *See* 4/2/10 Office Action, p. 7, ¶¶ 20-23. Indeed, it would not. As explained above, Gordon involves one-way transmission of information from the alleged drug delivery device (the blister package) to the alleged data carrier 64. There was no obvious reason to reverse this transmission direction so as to transmit treatment information from the Gordon’s data carrier 64.

For at least these reasons, Appellants respectfully request the reversal of this obviousness rejection of claim 40, as well as its dependent claims, which are patentable at least because they depend from a patentable independent claim.

C. The Rejection Of Claims 1, 13, 16-19, And 51-56 Under 35 U.S.C. § 103(a) As Obvious Over Anderson In View Of Gordon

Claims 1, 13, 16-19, and 51-56 were rejected under 35 U.S.C. § 103(a) as obvious over Anderson (U.S. Patent No. 5,237,987) in view of Gordon. Appellants traverse this rejection for the following reasons.

1. Independent Claim 13

Appellants respectfully traverse this rejection as applied to claim 13 for several reasons.

First, amended claim 13 recites, among other things, “a delivery controller configured to control the amount of the drug delivered to the patient based on the received treatment information.” The Office Action asserts that Andersen discloses “a delivery controller (28),” but fails to assert, much less prove that Andersen’s alleged controller (28) is “configured to control the amount of the drug delivered to the patient based on the received treatment information,” as recited in claim 13. *See* 4/2/10 Office Action, p. 8, ¶ 25. Indeed, Anderson discloses only that EPROMs are removably connected to Anderson’s controller 28 to “control various aspects of the individual subsystems.” Anderson, col. 12, line 58, to col. 13, line 3. Anderson does not disclose, suggest, or otherwise render it obvious that such a controller 28 is “configured to control the amount of the drug delivered to the patient based on the received treatment information,” as recited in claim 13.

Second, claim 13 recites, among other things, “a radio frequency receiver configured to receive the treatment information from the electronic data carrier over a radio frequency signal.” The Office Action concedes that Anderson fails to disclose such a combination of recitations, but nonetheless asserts that it would have been obvious “to use a radio frequency signal as an alternative to circuitry for transmitting information [from Anderson’s EPROMS to Anderson’s controller 28] because they are expedients of each other.” 4/2/10 Office Action, p. 8, ¶ 26. Appellants respectfully traverse such an assertion. Anderson’s EPROMS are physically embedded within Anderson’s controller 28. *See* Anderson, col. 12, line 58, to col. 13, line 3. There was no obvious rationale to have replaced the direct-hard-wired connection between the EPROMs inside the controller 28 and the controller 28 with a radio frequency connection. Specifically, a radio frequency connection is not an obvious “expedient” of Anderson’s hard-wired connection because such a change would be more complicated, and less reliable. In Anderson, the patient’s life depends on proper operation of the ventilator. Due to possible inherent reliability issues with radio frequency transmission (as opposed to Anderson’s direct wired connection), it would not have been obvious to transmit information on the EPROM embedded within the controller 28 to the controller 28. *See KSR Int’l. Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727, 1731, 82 USPQ.2d 1385, 1396 (2007) (stating that it is necessary to determine whether there was an “apparent reason” to combine the known elements in the claimed manner); *see also id.* (“[R]ejections on obviousness grounds cannot be sustained by mere

conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”).

Appellants therefore respectfully request the reversal of this obviousness rejection of claim 13, as well as its dependent claims, which are allowable at least because they depend from allowable independent claim 13.

2. Dependent Claim 16

Claim 16 recites, among other things, that “the electronic input is additionally configured to transmit treatment information to the electronic data carrier for recordal.” The Office Action fails to even allege that the proposed combination of Anderson in view of Gordon discloses such a combination of recitations. *See* 4/2/10 Office Action, p. 8, ¶ 27. Indeed, the proposed combination does not render this combination of recitations obvious. By their very definition, Anderson’s EPROM memories (i.e., “Erasable Programmable Read Only Memories”) (Anderson, col. 12, line 68, to col. 12, line 1) provide for one way data communication from the memories to the controller 28. There is no disclosure or suggestion in Anderson to modify such EPROM memories and Anderson’s controller 28 such that the controller 28 transmits treatment information to the EPROM memories.

Gordon does not cure this deficiency. The Office Action proposes that Gordon would have made it obvious to have incorporated a radio frequency signal into Anderson’s ventilation system, but does not assert that it would have been obvious to make any other modification to Anderson’s ventilation system in view of Gordon. *See* 4/2/10 Office Action, p. 8, ¶ 26. Accordingly, by the Office Action’s own account, Gordon does not render obvious any other modification to Anderson (e.g., modifying Anderson in view of Gordon such that Anderson’s controller 28 transmits treatment information to Anderson’s EPROM memories).

Moreover, even if the Office Action did allege that it was obvious to so modify Anderson in view of Gordon, the proposed modification would have been nonobvious. As explained above, Gordon is exclusively focused on patient compliance relating to the administration of capsules/tablets from a blister package. *See* 4/2/10 Office Action, p. 4, ¶ 12 ([Regarding claims 16-18], “[t]he Gordon reference is used as a teaching reference for only radio transmission of information.”). Such compliance and blister packages are irrelevant to Anderson’s use of a nebulizer for nebulizing a liquid medicament that is administered by a medical professional. Moreover, Gordon does not disclose two-way communication between an electronic data carrier

and an electronic input (e.g., an “electronic input ...to receive treatment information from a removable electronic data carrier” (claim 13), wherein the “electronic input is additionally arranged to transmit treatment information to the electronic data carrier for recordal”). Thus, Anderson and Gordon, either alone or in combination, fail to render obvious the combination of recitations in claim 16. Appellants therefore respectfully request the reversal of this obviousness rejection of claim 16 for this additional reason.

3. Dependent Claim 56

Claim 56 recites, among other things, that “the electronic input is configured to transmit treatment information via a radio frequency signal to the removable electronic data carrier.” In contrast, as explained above, Anderson’s drug delivery device is not configured to transmit treatment information from the drug delivery device to the electronic data carrier (i.e., alleged by the Office Action to be the EPROMs in the controller 28). Gordon does not cure this deficiency. Accordingly, Gordon and Anderson, both individually and in combination, fail to disclose or otherwise render obvious such a combination of recitations. The Office Action does not even allege, much less demonstrate, that the proposed combination would result in “the electronic input [being] configured to transmit treatment information via a radio frequency signal to the removable electronic data carrier,” as recited in claim 56. Appellants therefore respectfully request the reversal of this obviousness rejection of claim 56 for this additional reason.

4. Dependent Claim 17

Claim 17 recites, among other things, that “the drug delivery device includes an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery.” The Office Action asserts that “col. 12, lines 11-18” of Anderson disclose “an authorization portion.” 4/2/10 Office Action, p. 8, ¶ 27. To the contrary, the cited passage does not disclose such an authorization portion. Moreover, Anderson includes no disclosure whatsoever regarding the prevention of delivery of a drug if the drug is unsuitable for delivery. Indeed, Anderson includes only a cursory mention of the use of a “nebulizer 48 [to] add medication, such as for example a decongestant, to the gas flow 36.” Anderson, col. 6, lines 40-41. Gordon does not cure this deficiency. Appellants therefore respectfully request the reversal of this obviousness rejection of claim 17 for this additional reason.

5. Independent Claim 19

Appellants respectfully traverse this rejection as applied to claim 19 for several reasons.

First, claim 19 recites, among other things, “a memory located within the electronic data carrier; the memory holding drug-specific treatment information concerning the use of the drug delivery device in delivering a specified drug.” The Office Action asserts that Anderson’s EPROM memory satisfies this recitation. *See* 4/2/10 Office Action, p. 8, ¶ 25 (relying on Anderson, claim 5, which recites “memory devices,” which are EPROM memories, as explained in Anderson, col. 12, line 58, to col. 13, line 2). However, Anderson’s EPROM memories include information relating to the operation of Anderson’s ventilator, but do not include “drug-specific treatment information concerning the use of the drug delivery device in delivering a specified drug,” as recited in amended claim 19. Gordon does not cure this deficiency because, as explained above, Gordon’s blister-package-specific teaching has no obvious bearing on Anderson’s ventilation system’s use of a nebulizer.

Second, the proposed combination relies on replacing Anderson’s hard-wired connection between the EPROMs and the controller 28 with a radio frequency connection. Such a modification was nonobvious as explained above with respect to claim 13.

Appellants therefore respectfully request the reversal of this obviousness rejection of claim 19, as well as its respective dependent claims, which are allowable at least because they depend from allowable independent claim 19.

6. Dependent Claim 55

Appellants also specifically traverse this rejection as applied to claim 55, which depends from claim 20. Claim 20 was not rejected over any combination based on Andersen. The Office Action’s rejection of its dependent claim 55 as obvious over Andersen in view of Gordon is therefore improper because the Office Action fails to demonstrate that the proposed modified Andersen device would result in the combination of recitations in base claim 20. Appellants therefore respectfully request the reversal of this obviousness rejection of claim 55.

7. Independent Claim 1

Appellants respectfully traverse this rejection as applied to claim 1 for several reasons.

First, Appellants note that the Office Action provides no rationale or explanation as to how the proposed combination would result in the combination of recitations in claim 1. *See* 4/2/10 Office Action, pp. 7-8, ¶¶ 24-27. Although Appellants brought this shortcoming to the USPTO’s attention in response to a previous similarly deficient office action, the April 2, 2010

Office Action failed to cure this deficiency. *See* 6/3/09 Amendment, p. 21. Appellants therefore respectfully request the reversal of this rejection for at least this reason.

Second, Appellants presume that the prior art would be alleged to be combined in the same manner as asserted against claims 13 and 19. If so, the proposed combination would not have been obvious for the reasons explained above with respect to claims 13 and 19.

Appellants therefore respectfully request the reversal of this obviousness rejection of claim 1, as well as its dependent claims, which are allowable at least because they depend from allowable independent claim 1.

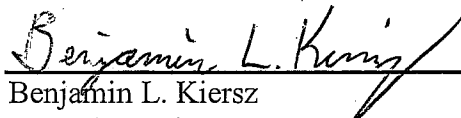
VIII. CONCLUSION

In view of the foregoing, Appellants request the reversal of the pending rejections of claims 1, 3, 7, 8, 12, 13, 16-21, 39-41, 44, and 51-63.

Having overcome all objections and rejections, Appellants therefore respectfully request allowance of the present application.

Please charge any fees associated with the submission of this paper to Deposit Account Number 14-1270. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,
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Enclosures: Appendix IX. Claims Appendix

Appendix X. Evidence Appendix
Appendix XI. Related Proceedings Appendix

IX. CLAIMS APPENDIX (37 C.F.R. § 41.37(c)(1)(viii))

The following pending claims 1, 3, 7, 8, 12, 13, 16-21, 39-41, 44, and 51-63 are being appealed.

1. A drug package comprising:
at least one container containing a drug for delivery to a patient in a drug delivery device; and

an electronic data carrier removable from the at least one container, the carrier including a memory holding drug treatment information for use by the drug delivery device, the electronic data carrier further includes a radio frequency device for transmitting the drug treatment information to the drug delivery device.

2. (Cancelled).

3. The drug package according to claim 1, wherein the drug is adapted for delivery in air inhaled by the patient to their lungs.

4. (Cancelled).

5. (Cancelled).

6. (Cancelled).

7. The drug package according to claim 1, wherein the electronic data carrier is arranged to supply the drug treatment information to the drug delivery device a number of times corresponding to the number of treatments available from the drug package, or to the number of containers included in the drug package.

8. The drug package according to claim 1, wherein the at least one container is a plurality of containers and wherein the electronic data carrier is a single electronic data carrier that includes the drug treatment information for each container.

9. (Cancelled).

10. (Cancelled).

11. (Cancelled).

12. The drug package according to claim 53, wherein:
the drug delivery device with which the drug is adapted to be used comprises a nebulizer;
the electronic data carrier further comprises a radio frequency receiver configured to receive nebulizer treatment information from the nebulizer; and
the memory is configured to store the nebulizer treatment information received from the nebulizer.

13. A drug delivery device comprising:
a delivery portion for delivering a drug to a patient;
an electronic input arranged remotely from the delivery portion and configured to receive treatment information from a removable electronic data carrier wherein the input is a radio frequency receiver configured to receive the treatment information from the electronic data carrier over a radio frequency signal; and
a delivery controller configured to control the amount of the drug delivered to the patient based on the received treatment information.

14. (Cancelled).

15. (Cancelled).

16. The drug delivery device according to claim 13, wherein the electronic input is additionally configured to transmit treatment information to the electronic data carrier for recordal.

17. The drug delivery device according to claim 13, wherein the drug delivery device includes an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery.

18. The drug delivery device according to claim 13, wherein the drug delivery device is selected from one of a pneumatic nebulizer, a piezo-electric nebulizer, or an ultrasonic nebulizer.

19. An assembly comprising:
a drug delivery device;
an electronic data carrier for use with the drug delivery device and removable from the drug delivery device, the electronic data carrier comprising:
a memory located within the electronic data carrier, the memory holding drug-specific treatment information concerning the use of the drug delivery device in delivering a specified drug, and
an output configured to transmit the drug-specific treatment information via a radio frequency signal from the memory to the drug delivery device.

20. A drug delivery system comprising:
a drug delivery device for delivering a drug, the drug delivery device having a medication chamber for receiving a drug for delivery and an electronic input for receiving treatment information relating to the drug; and
an electronic data carrier removable from the drug delivery device including a memory for storing the drug treatment information for use by the drug delivery device, the carrier also includes an output for transmitting the treatment information to the electronic input,
wherein the input is a radio frequency input which is configured to receive the treatment information from the electronic data carrier over a radio frequency signal, whereby the drug delivery device is configured to deliver the drug in conformity with the treatment information.

21. A method of operating a drug delivery device comprising:
supplying a plurality of containers, each container of the plurality of containers containing a drug for use with the drug delivery device;
supplying an electronic data carrier removable from the plurality of containers, the electronic data carrier includes treatment information;
transmitting the treatment information from the electronic data carrier to the drug delivery device;
placing an amount of the drug from a container of the plurality of containers in the drug delivery device; and
delivering the drug in accordance with the treatment information from the data carrier.

22-38. (Cancelled).

39. A drug package comprising:
a plurality of drug containers, each container containing a drug for delivery to a patient in a drug delivery device; and
an electronic data carrier separate from the drug containers, the carrier including drug treatment information for use by the drug delivery device wherein the data carrier is a radio frequency device and wherein the data carrier is arranged to be powered inductively from a radio frequency signal transmitted from or associated with the drug delivery device.

40. A drug package comprising:
a plurality of drug containers, each container containing a drug for delivery to a patient in a drug delivery device; and
an electronic data carrier separate from the drug containers, the carrier including drug treatment information for use by the drug delivery device wherein the data carrier is a radio frequency device, wherein the data carrier is arranged to be powered inductively from a radio frequency signal transmitted from or associated with the drug delivery device, and wherein the data carrier is arranged to generate the radio-frequency signal bearing the treatment information.

41. The drug package as recited in claim 61, wherein the drug treatment information includes at least one of the following items:

- a. an identity of the drug which is to be delivered;
- b. a security code;
- c. a desired dose amount;
- d. a desired frequency of treatments; or
- e. an expiration date of the drug.

42. (Cancelled).

43. (Cancelled).

44. The drug package as recited in claim 40, wherein the drug treatment information includes at least one of the following items:

- a. an identity of the drug which is to be delivered;
- b. a security code;
- c. a desired dose amount;
- d. a desired frequency of treatments; or
- e. an expiration date of the drug.

45-50. (Cancelled).

51. The assembly as recited in claim 19, wherein the drug delivery device is a nebulizer.

52. The assembly as recited in claim 51, wherein the nebulizer is selected from one of a pneumatic nebulizer, a piezo-electric nebulizer, or an ultrasonic nebulizer.

53. The drug package of claim 1, wherein the drug is configured for delivery to the patient via nebulization of the drug and inhalation of the nebulized drug by the patient.

54. The assembly of claim 19, wherein the drug delivery device comprises an electronic input configured to receive the treatment information from the output via the radio frequency signal.

55. The system of claim 20, wherein the drug delivery device comprises a nebulizer.

56. The drug delivery device of claim 13, wherein the electronic input is configured to transmit treatment information via a radio frequency signal to the removable electronic data carrier.

57. The drug package of claim 1, wherein:
the at least one container comprises a first container;
all of the drug in the first container is commonly stored in a single compartment of the first container; and
the drug treatment information comprises information indicating that some, but not all, of the drug in the first container should be delivered by the drug delivery device.

58. The drug package of claim 1, wherein the radio frequency device comprises a radio frequency transmitter configured to transmit the drug treatment information to the drug delivery device.

59. The method of claim 21, wherein the drug delivery device comprises a nebulizer.

60. The assembly of claim 19, wherein:
the radio frequency device comprises a radio frequency transmitter configured to transmit the drug treatment information; and
the drug delivery device comprises a radio frequency receiver configured to receive the drug treatment information transmitted by the radio frequency transmitter.

61. The drug package of claim 39, wherein the radio frequency device comprises a radio frequency transmitter configured to transmit the drug treatment information to the drug delivery device.

62. The drug package of claim 1, wherein the drug treatment information includes at least one of the following items:

- a. an identity of the drug which is to be delivered;
- b. a security code;
- c. a desired dose amount;
- d. a desired frequency of treatments; or
- e. an expiration date of the drug.

63. The drug package of claim 1, wherein the drug treatment information comprises drug-specific drug treatment information concerning the use of the drug delivery device in delivering the drug.

X. EVIDENCE APPENDIX (37 C.F.R. § 41.37(c)(1)(ix))

Appellants rely on the following evidence: none.

XI. RELATED PROCEEDINGS APPENDIX (37 C.F.R. § 41.37(c)(1)(x))

There are no decisions rendered by a court or the Board in any proceeding identified pursuant to 37 C.F.R. § 41.37(c)(1)(ii).